## REMARKS

The claims have been amended in order to more completely describe and distinctly claim the invention and to overcome the various grounds of rejection set forth in the Official Letter. Inasmuch as no new matter is embodied by the proposed amendments, entry thereof is respectfully requested.

The rejections of the claims under 35 USC 101/112, second paragraph is believed to be obviated by the above amendment whereby the objectionable term, "method", has been replaced with "product". Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 USC 102(b) as being completely anticipated or, in the alternative, under 35 USC 103(a) as being obvious over JP 61286327 is respectfully traversed.

The rejection under s5 USC 102(b) is fatally flawed in that the abstract thereof (on which the Examiner expressly relies as anticipatory of the claimed subject matter) does not identify the proportions of ingredients in the formulation disclosed with sufficient clarity to enable one skilled in the art to practice the skilled invention. Thus, the entire disclosure of the reference relied upon by the Examiner reads as follows:

> "---A topical pharmaceutical contains a small amt. of nitroglycerin for accelerating peripheral blood circulation and skin respiration. Thus, an ointment was prepd. consisting of nitroglycerin 10, lactose 90, 25% H20-contg. lanolin 600, and white Vaseline to 1000 g. The efficacy for treating frostbite in rats was demonstrated---".

It is apparent that one skilled in the art would be unable to prepare any product based on the information contained in the above passage since no, or, at the very least, confusing parameters are set forth for the various numbers recited. For example, the reference states "nitroglycerin 10". The question, 10 what?, is raised. Since other parts of the passage refer to

%s or grams, does the numeral, "10", indicate 10% or 10 grams of nitroglycerin? The same is true with respect to the reference to "lanolin 600; 600 what?

Since the present claims specify amounts of the recited ingredients effective to treat erectile dysfunction and the reference relied upon does not identify such amounts, it cannot be said to anticipate the invention. It is, of course, well settled that "a prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation" (*Minnesota Mining and Manufacturing Co. v. Chemique, Inc.* 303 F3d 1294, 64 USPQ2d 1270 (Fed. Cir. 2002)). In *In re Wands*, 858 F2d 721, 8 USPQ2d 1400 (Fed. Cir. 1998), it is stated that the factual premises of enablement in a prior art reference may include the following:

(1.) the quality of experimentation necessary;

(2.) the amount of direction and guidance given;

(3.) the nature of the invention;

(4.) the state of the prior art;

(5.) the relative skill of those in the art;

(6.) the predictability or unpredictability of the art; and

(7.) the breadth of the claims.

It is readily apparent that the reference relied upon fails on all seven counts to qualify as an enabling disclosure of the claimed invention. See also In re Legrice, 133 USPQ 365; Phillips v. Ladd, 138 USPQ 421; DuPont v. Ladd 140 USPQ 297; In re Brown, 141 USPQ 254; In re Foster 145 USPQ 166; In re Dow, 5 USPQ2d 1529; In re Grose, 201 USPQ 57, and In re Wiggins, 179 USPQ 421.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Nor does JP 61286327 render the claimed invention obvious, either alone or in view of Heaton. JP61286327 discloses a topical pharmaceutical composition falling within having

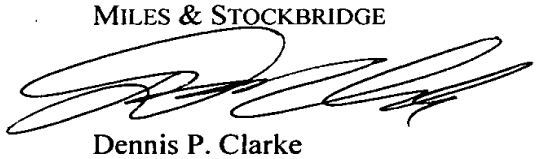
a utility only for the treatment of frostbite in rats. The Heaton et al article in the Journal of Urology refers to the use of a nitroglycerine paste applied to the penis for the purpose of treating erectile dysfunction but there is no indication whatsoever, in the article, as to the ingredients of the paste. There is nothing in either reference to suggest the claimed invention except a hindsight reconstruction of thereof from disparate and unrelated disclosures, utilizing the present specification as a template.

Moreover, the Heaton article reports that 40% of the subjects tested with the disclosed formulation complained of headache. This portion of the disclosure contraindicates the safety and efficacy of the reference composition, thereby teaching against the claimed invention. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

Respectfully submitted,

MILES & STOCKBRIDGE



Dennis P. Clarke
Registration No. 22,549

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CUSTOMER NO. 000181

1751 Pinnacle Drive
Suite 500
McLean, VA 22102-3833
Telephone: (703) 903-9000
Facsimile: (703) 610-8686